K003118

DEC 2 0 2000

APPENDIX 8

510(K) SUMMARY

Submitted by:
Zynergy CardioVascular, Inc.
298 Fernwood Ave.
Edison, NJ 08837

Oct. 3, 2000

This 510(k) Summary of Safety and Effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

1. Contact Person:

Ms. Jing Zhang
Manager, Regulatory Affairs/Quality Assurance
Zynergy CardioVascular, Inc.
298 Fernwood Ave.
Edison, NJ 08837
Phone: (732)225-3800 Fax: (732)225-4454

2. Device Name and Classification:

- Trade name: Z2 Balloon Guided Pacing and Pressure Monitoring Catheter
- Common / Usual Name: Flow Directed Pacing and Monitoring Catheter
- Classification Name: LDF - Electrode, Pacemaker, Temporary, CFR 870.3680
- DYG - Catheter, flow directed, CFR 870.1240
- Classification Panel: Cardiovascular
- Device Class: Class II

3. Substantial Equivalence:

The Z2 Balloon Guided Pacing and Pressure Monitoring Catheter is substantially equivalent to the following two predicate devices:

1) Elecath Ventricular Pacing Wedge Pressure Catheter
Electro-Catheter Corporation

And

2) Swan-Ganz Flow Directed Pressure TD Catheter
Baxter Healthcare Co.

4. Device Description:

The Z2 catheter was designed and tested in accordance with the applicable sections of ISO 10555-1:1995, Sterile, Single-Use Intravascular Catheters - Part 1: General Requirements. It is constructed from a four lumen polyurethane tube. The tubing is radiopaque and is 7 Fr in diameter. One lumen opens at the distal tip for pressure monitoring, infusion, and/or aspiration. A second lumen opens 30 cm from the tip to monitor intravascular pressures or

administer infusates (e.g., saline or medications or solutions) or aspirate fluids (e.g., blood). A latex balloon is mounted at the distal tip for flow-directed placement of the catheter and monitoring wedge pressures. Two platinum 5 mm ring electrodes are spaced 1 cm apart on the shaft of the catheter. They are used for EKG monitoring and bipolar ventricular pacing. The catheter is marked at 10 cm intervals with bands to indicate distance from the distal tip. A molded junction is on the proximal end of the catheter tubing which provides attachment for lead wire assemblies and lumen access. The distal and proximal lumens terminate in color coded and marked female luer lock fittings. The lumen for balloon inflation terminates in a stopcock. The maximum balloon inflation volume is marked on the extension tube leading to the stopcock. The electrode leads terminate in color coded lead wires with shrouded pin connectors for attachment to an external pulse generator. These pin connectors meet the Performance Standard for Electrode Lead Wires and Patient Cables.

The catheter is packaged with a volume limited syringe as a single use disposable device and shipped ETO sterilized.

5. Intended Use of the Device:
The Z2 catheter is indicated for use in temporary transvenous ventricular cardiac pacing and monitoring for impaired impulse formation or conduction. In addition, the specialized lumens of the catheter may be utilized for monitoring intra cardiac blood pressure and fluid administration.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:
The Z2 catheter has similar technological characteristics like the predicate Elecath and Baxter catheters. They are all 7 Fr. in size and 110 cm in working length. The intended anatomical location of the distal end, for all catheters, is pulmonary artery and right heart. All catheters have depth marking, open tip design, straight tip curves, and latex balloon with inflation capacity to 1.5 cc. They all are radiopaque, packaged with a volume limited syringe, ETO sterilized with 10^{-6} SAL.

The Z2 catheter is almost identical to the Elecath catheter except for the catheter material and balloon size. The differences between Z2 catheter and the predicate Baxter catheters are in material of the catheter, and electrode design (size, spacing, number of electrodes). However, the differences between the Z2 catheter and the predicate devices do not raise any new issues of safety or effectiveness as demonstrated by the comparable results of the functional and performance testing.

7. Tests and Conclusions:
Extensive functional and performance testing, and biocompatibility testing were conducted to assess the safety and effectiveness of the Z2 catheter. All results are satisfactory.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2000

Ms. Jing Zhang
Manager, RA/QA
Zynergy CardioVascular, Inc.
298 Fernwood Avenue
Edison, NJ 08837-3839

Re: K003118
Trade Name: Z2 Balloon Guided Pacing and Pressure Monitoring Catheter
Regulatory Class: Class II (two)
Product Code: DYG
Dated: October 3, 2000
Received: October 5, 2000

Dear Ms. Zhang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the kit/tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit/tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices:

General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (FDA) may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal Laws or Regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

APPENDIX 6
INDICATIONS FOR USE

510(k) Number (if known): K003118

Device name: Z2 Balloon Guided Pacing and Pressure Monitoring Catheter

Indications For Use:

Z2 Balloon Guided Pacing & Pressure Monitoring Catheter is indicated for use in temporary transvenous ventricular cardiac pacing and monitoring for impaired impulse formation or conduction. In addition, the specialized lumens of the catheter may be utilized for monitoring intra cardiac blood pressure and fluid administration.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K003118

Prescription Use ✓ **OR Over The Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)